

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include Figures 1-3. These sheets, which include Figures 1-3, represent a separate submission of the drawings as required by the Examiner to conform with U.S. practice.

Attachment: 2 New Sheets of Drawings including FIGS. 1-3 as originally filed in the Specification.

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-11 and 15-17 are pending in this application. Claims 12-14 and 18-20 have been cancelled. Claims 1 and 11 have been amended. Claim 1 is the independent claim.

Applicants note with appreciation the Examiner's acknowledgement that certified copies of all priority documents have been received by the U.S.P.T.O. Action, summary at 12.

Drawings

The Examiner states that the Applicant is required to submit drawings separately, not as part of the specification, and include a section titled "Brief Description of the Drawings" in the Specification. Applicants respectfully submit that the amendments to add headings as shown in the Substitute Specification and the separate submission of FIGS. 1-3 reflected in the attached sheets are sufficient to conform the drawings and the specification text with U.S. practice and request that this objection be reconsidered and withdrawn accordingly.

Example Embodiments of the Present Application

Independent claim 1 recites forming stabilized silicic acid, by hydrolysing a silicon compound into orthosilicic acid and/or oligomers thereof in the presence of a stabilizing agent, which is a quaternary ammonium compound, or an amino-acid, or an amino acid source or combinations thereof. Example non-limiting embodiments of this feature are discussed, for example, on page 2, lines 9-20 of the instant specification. In example embodiments, a stabilizing compound is used including a

nitrogen group, although these compounds are known to be highly hygroscopic, e.g., choline chloride.

Rejections under 35 U.S.C. § 103(a)

Vanden Berghe/Bronder

Claims 1-4, 6-11, and 15-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Vanden Berghe (EP 1 110 909 A1) in view of Bronder (US 5,922,360). Applicants respectfully traverse this rejection for the reasons detailed below.

The outstanding Office Action on page 4, lines 8-9, acknowledges that Vanden Berghe fails to disclose the stabilization of orthosilicic acid with a stabilizing agent such as quaternary ammonium compound and relies on the teachings of Bronder for this feature of claim 1.

Vanden Berghe relates to providing a *solid* formation of stabilized silicic acid by extrusion, and this is achieved by an “acid solvent agent” as a component to the formulation. The solvent agent used in Vanden Berghe has a boiling point higher than 130°C, and is in liquid state between -10 and 40°C (par. 7 of Vanden Berghe, last sentence: “A common set of properties for all solvent agents are...”). The teaching of Vanden Berghe is thus that the solvent agent should be a liquid at -10 and 40°C. The resulting extrudate can be finely pelletized for further formation of dosage forms.

Bronder is directed to providing a *liquid preparation* of orthosilicic acid stabilized by a stabilizing agent. Although Bronder gives some general suggestions to provide solid preparations, these suggestions are not at all directed to an extrusion process, to obtain a solid that can be further processed. Bronder only discloses

mixing a solid sugar/maltose carrier in the liquid preparation, which is directly pressed into tablets (Formulation example C).

In hindsight, the skilled person *would not have been motivated to try* using the stabilizing agent of Bronder in the method of Vanden Berghe, because the stabilizing agent of Bronder does not fulfill the criteria of boiling point and liquid state as defined for the solvent agent of Vanden Berghe. For instance, all stabilizing agents disclosed in Bronder are *solid* compounds at room temperature, i.e., -10 and 40°C. The skilled person would also recognize that such a change of a formulation would largely affect the subsequent extrusion process which is sensitive to the exact composition of a formulation that is extruded.

Therefore, Applicants respectfully submit that incorporating the stabilizing agent of Bronder into the method of preparing a silicic acid by extrusion described in Vanden Berghe would change the basic operation of the method described in Vanden Berghe, which requires that the solvent agent have a boiling point higher than 130°C, and be in liquid state between -10 and 40°C. As such, there is insufficient evidence in the record for modifying the method of preparing a silicic acid by extrusion of Vanden Berghe to incorporate the stabilizing agent of Bronder.

The Applicants, therefore, respectfully request that the rejection to Claim 1 under 35 U.S.C. § 103(a) be withdrawn.

Claims 2-4, 6-11, and 15-16, dependent on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 1 and all claims dependent thereon.

Vanden Berghe/Bronder/Sequin

Claims 5 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vanden Berghe (EP 1 110 909 A1) in view of Bronder (US 5,922,360) and further in view of Seguin et al. (US 6,335,457).

With respect to claims 5 and 17, Applicants incorporate the discussion presented above with respect to the deficiencies of Vanden Berghe and Bronder to teach or suggest the method for preparing a silicic acid as recited in claim 1. As claims 5 and 17 depend from claim 1, Applicants submit that claims 5 and 17 are equally allowable over the applied references.

The Applicants, therefore, respectfully request that the rejection to Claims 5 and 17 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKY, & PIERCE, P.L.C.

By



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Attachments: Drawing Sheets including FIGS. 1-3 (2)
 Substitute Specification (Clean and Redline)